



BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1314

[Docket No. DEA-328]

RIN 1117-AB25

Implementation of the Methamphetamine Production Prevention Act of 2008

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final Rule.

SUMMARY: In October 2008, the President signed the Methamphetamine Production Prevention Act of 2008 (MPPA), which clarifies the information entry and signature requirements for electronic logbook systems permitted for the retail sale of scheduled listed chemical products. On March 23, 2010, DEA published a Notice of Proposed Rulemaking to implement the provisions of the MPPA and make its regulations consistent with the new requirements. This action finalizes without change the Notice of Proposed Rulemaking published on March 23, 2010. The Final Rule will make it easier for regulated sellers to maintain electronic logbooks by allowing greater flexibility as to how information may be captured.

EFFECTIVE DATE: [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Rhea D. Moore, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone (202) 307-7165.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801-971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1321. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and to deter the diversion of controlled substances to illegal purposes.

The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture and distribution of chemicals that may be used to manufacture controlled substances illegally. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

Background

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act

of 2005 (Pub. L. 109-177). CMEA amended the CSA to regulate the sale of products that contain ephedrine, pseudoephedrine, and phenylpropanolamine, their salts, optical isomers, and salts of optical isomers, that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as nonprescription drugs. CMEA defines these products as “scheduled listed chemical products” (21 U.S.C. 802(45)). Ephedrine, pseudoephedrine, and phenylpropanolamine are List I chemicals because they are used in, and important to, the illegal manufacture of methamphetamine and amphetamine, both Schedule II controlled substances. The Methamphetamine Production Prevention Act of 2008 (MPPA) (Pub. L. 110-415) was enacted in 2008 to clarify the information entry and signature requirements for electronic logbook systems permitted for the retail sale of scheduled listed chemical products. On March 23, 2010, DEA published a Notice of Proposed Rulemaking to implement the provisions of the MPPA and make its regulations consistent with the new requirements. 75 FR 13702. This finalizes that proposed rulemaking.

Requirements for Retail Sales of Scheduled Listed Chemical Products

CMEA defines nonprescription drug products marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act containing ephedrine, pseudoephedrine, or phenylpropanolamine as "scheduled listed chemical products" (21 U.S.C. 802(45)). Direct, in-person sales to a customer, whether by a regulated seller (e.g., grocery store, general merchandise store, drug store) (21 U.S.C. 802(46), (49)) or a mobile retail vendor (e.g., kiosk, flea market), (21 U.S.C. 802(47)) are subject to requirements for training of employees who either are responsible for delivering scheduled listed chemical products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products (21 U.S.C. 830(e)(1)(A)(vii)). The regulated seller must certify to DEA that the

employees have been trained (21 U.S.C. 830(e)(1)(B)). These regulated sellers must also check identifications of purchasers and maintain specific records (the logbook) of each sale of scheduled listed chemical products (21 U.S.C. 830(e)(1)(A)). The only sales exempt from recordkeeping are sales of single packages where the package contains not more than 60 milligrams of pseudoephedrine (21 U.S.C. 830(e)(1)(A)(iii)).

On September 26, 2006, DEA published in the Federal Register an Interim Final Rule, “Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products” (71 FR 56008; corrected at 71 FR 60609, October 13, 2006). That rule incorporated the standards set forth by the CMEA, requiring regulated sellers of scheduled listed chemical products to maintain logbooks regarding their sales on and after September 30, 2006. If a regulated seller maintains the logbook on paper, DEA requires that the book be bound, as is currently the case for records of sales of Schedule V controlled substances that are sold without a prescription (21 CFR 1314.30(a)(2)). The records must be readily retrievable and available for inspection and copying by DEA or other State or local law enforcement agencies (21 U.S.C. 830(e)(1)(C)(i), 21 CFR 1314.30(i)). Logs must be kept for not fewer than two years from the date the entry was made (21 CFR 1314.30(g)). CMEA required the logs include the information entered by the purchaser (name, address, signature, date and time of sale) and the quantity and form of the product sold.

DEA permitted by regulation that where the record was entered electronically, the computer system may enter the date and time automatically. An electronic signature system, such as the ones many stores use for credit card purchases, could be employed to capture the signature for electronic logs (21 CFR 1314.30(c)). The information that the seller must enter could be accomplished through a point-of-sales system and bar code reader.

Changes to § 1314.30

On October 14, 2008, the President signed the MPPA. The Act amended the existing language in 21 U.S.C. 830(e)(1)(A) by revising clauses (iv) through (vi). The purpose of this Act was to facilitate the creation of electronic logbooks. Several options were provided for obtaining signatures of purchasers and recording transactions at the time of the sale.

Specifically, the requirements now state that a regulated seller of scheduled listed chemical products may not sell such a product unless the purchaser:

- Presents a government issued photographic identification; and
- Signs the written logbook with his or her name, address, time and date of the sale, or signs in one of the following ways:
 - In the case of an electronic logbook, the device must capture the signature in an electronic format.
 - In the case of a bound paper book, a printed sticker must be affixed to the book at the time of sale adjacent to the signature line. The sticker must display the product name, quantity, name of purchaser, date and address, or a unique identification that can be linked to that information.
 - In the case of a printed document, the document must include a clear line for the purchaser's signature and include product name, quantity, name and address of purchaser, and date and time of sale.

The MPPA expressly permits the regulated seller to capture information regarding the name of the product and the quantity sold through bar code, electronic data capture, or similar technology. The regulated seller remains responsible for determining that the name entered corresponds to the photographic identification presented by the purchaser. The MPPA indicates

that if the prospective purchaser enters the information into the logbook, the regulated seller must determine that the name entered in the logbook corresponds to the name provided on the photographic identification and must determine that the date and time of the sale as entered by the purchaser are correct. If the regulated seller enters the information into the logbook, the prospective purchaser must verify that the information is correct.

In addition, the written or electronic logbook must continue to include a notice to purchasers that entering false statements or misrepresentations in the logbook, or supplying false information or identification that results in the entry of false statements or misrepresentations, may subject the purchaser to criminal penalties under section 1001 of title 18 of the U.S. Code (21 U.S.C. 830(e)(1)(A)(v)). The logbook must be maintained by the regulated seller for not fewer than two years after the date on which the entry is made (21 U.S.C. 830(e)(1)(A)(vi)).

The changes made by the MPPA and implemented in this rulemaking will provide greater flexibility for regulated sellers of scheduled listed chemical products. These persons may now choose several alternative ways in which to capture and maintain required logbook information: a fully written logbook, a fully electronic logbook, or a logbook where some information is captured electronically and the prospective purchaser's signature is captured and linked to that information.

Discussion of Comments

DEA received one comment on its Notice of Proposed Rulemaking. An association representing chain drug stores commented that the proposed rule allowed for flexibility in complying with Federal and State logbook requirements. The commenter also stated that the proposed rule was both logical and time-saving. By allowing regulated sellers to scan purchaser

identifications, the proposed rule makes it possible for regulated sellers to simultaneously check purchaser identification and electronically capture purchaser information.

DEA appreciates the support for its Notice of Proposed Rulemaking regarding the implementation of the MPPA, and is finalizing the Proposed Rule without change.

Regulatory Analyses

Executive Orders 12866 and 13563

This final rule implementing the MPPA has been developed in accordance with the principles of Executive Orders 12866 and 13563. As discussed above, this action incorporates statutory provisions into existing regulations. This statutory change imposes no new costs on regulated sellers of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Rather, it provides greater flexibility for regulated sellers who may choose to capture required logbook information in a written form, in an electronic form, or in a manner that combines written and electronic information. While not economically significant, this final rule has been reviewed by the Office of Management and Budget.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law, impose enforcement responsibilities on any State, or diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 13175

This rule is required by statute, will not have tribal implications and will not impose substantial direct compliance costs on Indian tribal governments.

Regulatory Flexibility Act

This rule has been reviewed in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Deputy Assistant Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule simply incorporates the statutory provisions of the MPPA into existing regulations. This rule will provide greater flexibility to regulated sellers, permitting them to capture required logbook information in a variety of ways.

Paperwork Reduction Act of 1995

Although the requirements of the MPPA revise the ways in which logbook information may be captured or presented, these requirements are not substantially different than the previously existing requirements for documentation of sales in logbooks. DEA believes that these revised requirements will have a negligible impact on the time estimated to document a sale. Estimates of this time burden are included in information collection 1117-0046, “Certification, Training, and Logbooks for Regulated Sellers of Scheduled Listed Chemical Products.” Therefore, as DEA does not believe that the burden associated with this collection will measurably change, DEA is not revising this information collection.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$136,000,000 or more (adjusted for inflation) in any one

year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more, a major increase in costs or prices, or have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1314:

Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR Part 1314 is amended as follows:

PART 1314-- RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS

1. The authority citation for Part 1314 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 842, 871(b), 875, 877, 886a.

2. Section 1314.30 is revised to read as follows:

§ 1314.30 Recordkeeping for retail transactions.

(a) Except for purchase by an individual of a single sales package containing not more than 60 milligrams of pseudoephedrine, the regulated seller must maintain, in accordance with criteria issued by the Administrator, a written or electronic list of each scheduled listed chemical product sale that identifies the products by name, the quantity sold, the names and addresses of the purchasers, and the dates and times of the sales (referred to as the “logbook”).

(b) The regulated seller must not sell a scheduled listed chemical product at retail unless the sale is made in accordance with the following:

(1) The purchaser presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of 8 CFR 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B).

(2) The purchaser signs the logbook as follows:

(i) For written logbooks, enters in the logbook his name, address, and the date and time of the sale.

(ii) For electronic logbooks, provides a signature using one of the following means:

(A) Signing a device presented by the seller that captures signatures in an electronic format. The device must display the warning notice in paragraph (d) of this section. Any device used must preserve each signature in a manner that clearly links that signature to the other electronically-captured logbook information relating to the prospective purchaser providing that signature.

(B) Signing a bound paper book.

(I) The bound paper book must include, for such purchaser, either—

(i) A printed sticker affixed to the bound paper book at the time of sale that either displays the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale, or a unique identifier which can be linked to that electronic information, or

(ii) A unique identifier that can be linked to that information and that is written into the book by the seller at the time of sale.

(2) The purchaser must sign adjacent to the printed sticker or written unique identifier related to that sale. The bound paper book must display the warning notice in paragraph (d) of this section.

(C) Signing a printed document that includes, for the purchaser, the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale. The document must be printed by the seller at the time of the sale. The document must contain a clearly identified signature line for a purchaser to sign. The printed document must display the warning notice in paragraph (d) of this section. Each signed document must be inserted into a binder or other secure means of document storage immediately after the purchaser signs the document.

(3) The regulated seller must enter in the logbook the name of the product and the quantity sold. Examples of methods of recording the quantity sold include the weight of the product per package and number of packages of each chemical, the cumulative weight of the product for each chemical, or quantity of product by Universal Product Code. These examples do not exclude other methods of displaying the quantity sold. Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology. Such electronic records must be provided pursuant to paragraph (g) of this section in a human readable form such that the requirements of paragraph (a) of this section are satisfied.

(c) The logbook maintained by the seller must include the prospective purchaser's name, address, and the date and time of the sale, as follows:

(1) If the purchaser enters the information, the seller must determine that the name entered in the logbook corresponds to the name provided on the identification and that the date and time entered are correct.

(2) If the seller enters the information, the prospective purchaser must verify that the information is correct.

(3) Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(d) The regulated seller must include in the written or electronic logbook or display by the logbook, the following notice:

WARNING: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than \$250,000 if an individual or \$500,000 if an organization, imprisoned not more than five years, or both.

(e) The regulated seller must maintain each entry in the written or electronic logbook for not fewer than two years after the date on which the entry is made.

(f) A record under this section must be kept at the regulated seller's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated seller if the regulated seller has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.

(g) The records required to be kept under this section must be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of section 510 of the Act (21 U.S.C. 880).

(h) A record developed and maintained to comply with a State law may be used to meet the requirements of this section if the record includes the information specified in this section.

Dated:
November 22, 2011

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

[FR Doc. 2011-30630 Filed 11/30/2011 at 8:45 am; Publication Date: 12/01/2011]